

UNITED STATES SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

BE IT KNOWN that we, Kenneth McCadden and Grace McCadden, citizens of the United States, having an address of 54 Knollwood Drive, Carle Place NY 11514, have invented certain new and useful improvements in a

HANGOVER TREATMENT

of which the following is a specification.

## CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/418,777 filed October 16, 2002

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention

This invention relates to the treatment and prevention of alcohol induced hangovers by the administration of the compound methylsulfonylmethane.

### 2. The Prior Art

The term "alcohol" as used herein refers to ethyl alcohol and "alcoholic beverages" refers to popular spirits or blends that are intended for human consumption.

The social and economic consequences of alcohol overindulgence are well documented. Studies have indicated that approximately 1400 college students die each year as a result of unintentional alcohol-related injuries, including motor vehicle collisions, and 500,000 college students are unintentionally injured each year in alcohol-related

incidents. (Hingson, R.W.; Heeren, T.; Zakocs, R.C.; et al. Magnitude of alcohol-related mortality and morbidity among U.S. college students ages 18-24. *Journal of Studies on Alcohol* 63(2), 2002). Alcohol use among college students has been linked to assault, sexual abuse, vandalism and other criminal activity. (Hingson et al.; Wechsler H., Lee J.E., Kuo M., Seibring M., Nelson T.F., Lee H.P., Trends in college binge drinking during a period of increased prevention efforts: Findings from four Harvard School of Public Health study surveys, 1993-2001. *Journal of American College Health* 50(5), 2002). Additionally, alcohol use and abuse is related to health and academic problems among college students. (Hingson et al., Wechsler et al.).

The after effects of over-consumption of alcoholic beverages are well-known and are manifested in symptoms which include headache, nausea, dizziness, loss of appetite, dehydration and body aches. These symptoms are commonly referred to, collectively and individually, as a hangover.

There are many products available which are claimed to be effective in the treatment of alcohol induced hangovers. They include aspirin as well as various natural ingredients

and combinations of natural ingredients which are to be ingested before, during and/or after alcohol consumption. Additionally there are known many "folk" hangover cures from around the world, for example consuming a large T-bone steak or a chocolate milk shake (Australia); consuming thick, hot onion soup (France); rubbing a lemon under the arm used for drinking (Puerto Rico); consuming heavily salted cucumber juice or black bread soaked in water (Russia); and consuming a sip of brandy with a dash of peppermint (Switzerland).

Methylsulfonylmethane, also known as MSM or organic sulfur, is a naturally occurring sulfur compound found within the human body. It is not a sulfate or a sulfite. The toxicity level of methylsulfonylmethane is similar to water and is 1/7 that of common table salt.

Methylsulfonylmethane is stored in the cells of the human body and of the minerals present in the body, methylsulfonylmethane ranks third in quantity. The body uses approximately 1/8 of a teaspoon of methylsulfonylmethane each day. Excess methylsulfonylmethane is not stored by the body but rather is excreted in the manner of vitamin C.

Methylsulfonylmethane is present naturally in foods and mammal's milk, however the amount of methylsulfonylmethane consumed by humans is depleted as a result of food processing. Methylsulfonylmethane has been used in the treatment of arthritis, osteoarthritis, lupus, bursitis, gout and kidney stones. Published patents concerning the use of methylsulfonylmethane to prevent, treat or relieve various conditions include: U.S. Patent Nos. 6,440,391 and 5,569,679 (management of snoring); 4,973,605 (relief of pain and nocturnal cramps and reduction of stress-induced death in animals); 4,568,547 (use as an excipient in tableting and encapsulating pharmaceutical dosage forms); 4,559,329 (reduction of gastric upset and allergic reactions); and 4,447,469 (as a topical preparation to soften skin, nails and other tissues).

#### SUMMARY OF THE INVENTION

The invention relates to the treatment and prevention of alcohol induced hangovers by the administration of the compound methylsulfonylmethane. In a first embodiment, approximately 0.06 ounces of substantially pure methylsulfonylmethane in powdered form are mixed with approximately eight ounces of juice or water and administered

to a person who is experiencing the symptoms of an alcohol-induced hangover. In another embodiment, a therapeutically effective amount of methylsulfonylmethane is incorporated into a solid oral dosage form, such as a tablet or capsule and administered to a person who is experiencing the symptoms of an alcohol-induced hangover.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Essentially, the invention relates to the treatment and prevention of an alcohol induced hangover by administering the compound methylsulfonylmethane. When a person ingests alcoholic beverages, the alcohol enters and remains in the cells of the body and prevents the uptake of oxygen by the cells. This results in the unpleasant feelings associated with an alcohol induced hangover. Methylsulfonylmethane causes the cell walls to become slippery and softer, allowing alcohol to be flushed out and oxygen to enter the cells and relieve the hangover symptoms.

In a first embodiment, approximately 0.06 ounces of substantially pure methylsulfonylmethane powder are mixed with approximately eight ounces of water or juice. The water may be plain or distilled. The mixture is then administered

to a person who is experiencing the symptoms of an alcohol induced hangover. The after-effects of alcohol consumption, for example headache, nausea, dizziness, loss of appetite, dehydration and body aches are typically eliminated within approximately ½ hour of administration.

Substantially pure methylsulfonylmethane powder may be packaged in a packet, package or envelope known in the art. Each packet, package or envelope may comprise an individual dose, for example 0.06 ounces of substantially pure methylsulfonylmethane powder.

In a second embodiment, methylsulfonylmethane is administered to a person prior to that person's consumption of alcohol. The onset of symptoms associated with an alcohol induced hangover is thereby prevented.

In another embodiment, the methylsulfonylmethane compound is incorporated into a solid oral dosage form, such as a tablet or capsule, and ingested by a person who is experiencing the symptoms of an alcohol induced hangover.

When incorporated into a solid dosage form, such as a tablet or capsule, the solid dosage form may be packaged, for example in a bottle, blister pack, box, carton or any suitable packaging known in the art.

#### EXPERIMENTAL RESULTS

Eight subjects (four male and four female) participated in a focus group to demonstrate the effectiveness of methylsulfonylmethane in treating an alcohol induced hangover. Each subject consumed an average of 9.5 alcoholic drinks in an average time period of 4.1 hours over the course of one evening. Each subject reported that they experienced the effects of an alcohol induced hangover the following morning. Upon rising, the subjects each ingested approximately 0.06 ounces of methylsulfonylmethane powder which had been mixed with approximately 8 ounces of water or juice. Each subject attested to the fact the effects of their alcohol induced hangover were relieved within less than one hour after ingesting the methylsulfonylmethane compound.

While several embodiments of the present invention have been described, it is obvious that many changes and



modifications may be made thereunto without departing from the spirit and scope of the invention.